CLAIMS

We claim:

1. A method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a FoxA2 therapeutic.

2. The method of claim 1 wherein the FoxA2 therapeutic is an agent selected from the group consisting of an isolated FoxA2 protein, an isolated nucleic acid molecule encoding a FoxA2 protein, a FoxA2 receptor-specific antibody that stimulates the activity of the receptor, or pharmaceutically acceptable composition thereof.

3. The method of claim 2, wherein the FoxA2 therapeutic agent is a FoxA2 receptor-specific antibody that stimulates the activity of the receptor.

4. The method of claim 2, wherein the FoxA2 therapeutic agent is an isolated FoxA2 protein or proFoxA2 protein.

5. The method of claim 2, wherein the FoxA2 therapeutic agent is an isolated nucleic acid molecule encoding a FoxA2 protein or proFoxA2 protein, wherein the nucleic acid molecule is operatively linked to a transcription control sequence.

6. The method of claim 5, wherein the nucleic acid molecule is expressed in the subject's airway cells.

7. The method of claim 6, wherein the nucleic acid that encodes a FoxA2 polypeptide, fragment, homolog or variant with substantial homology, supplying FoxA2 function.

8. The method of claim 7, wherein the nucleic acid molecule becomes integrated to the chromosomal DNA making up the genome of the subject's airway cells.

9. The method of claim 7, wherein the nucleic acid molecule is expressed by the subject's airway cells from an extrachromosomal location.

10. The method of claim 7, wherein the nucleic acid molecule comprises at least 50 nucleotides.

11. The method of claim 7, wherein the nucleic acid molecule comprises at least 200 nucleotides.

12. The method of claim 7, wherein the airway cells are selected from the group consisting of smooth muscle and epithelial cells.

13. The method of claim 7, wherein the isolated nucleic acid molecule is administered to the mammal complexed with a liposome delivery vehicle.

14. The method of claim 7, wherein the isolated nucleic acid molecule is administered to the mammal in a viral vector delivery vehicle.

15. The method of claim 14, wherein the viral vector delivery vehicle is from adenovirus.

16. The method of claim 7, wherein the isolated nucleic acid molecule, when administered to the lungs of the mammal, is expressed in cells of the mammal.

17. The method of claim 2, wherein the disease is a chronic obstructive pulmonary disease of the airways associated with eosinophilic inflammation.

18. The method of claim 2, wherein the disease is selected from the group consisting of airway obstruction, allergies, asthma, acute inflammatory lung disease, chronic inflammatory lung disease, chronic obstructive pulmonary dysplasia, emphysema, pulmonary emphysema, chronic obstructive emphysema, adult respiratory distress syndrome, bronchitis, chronic bronchitis, chronic asthmatic bronchitis, chronic obstructive bronchitis, and interstitial lung diseases.

19. The method of claim 2, wherein the FoxA2 therapeutic agent decreases lung inflammation in the mammal.

20. The method of claim 2, wherein the FoxA2 therapeutic agent is administered in an amount between about 0.1 micrograms/kilogram and about 10 milligram/kilogram body weight of a mammal.

21. The method of claim 2, wherein the FoxA2 therapeutic agent is administered in a pharmaceutically acceptable excipient.

22. The method of claim 2, wherein the mammal is a human.

23. The method of claim 1, wherein the FoxA2 therapeutic agent is administered by at least one route selected from the group consisting of nasal and inhaled routes.

24. The method of claim 2, wherein the pulmonary disease is selected from the group consisting of asthma, allergic bronchopulmonary aspergillosis, hypersensitivity pneumonia, eosinphilic pneumonia, allergic bronchitis bronchiectasis, hypersensitivity pneumotitis, occupational asthma, reactive airway disease syndrome, hypereosinophilic syndrome, rhinitis, sinusitis, and parasitic lung disease.

25. A method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response in a mammal, comprising: a. administering to the lungs of a mammal a FoxA2 therapeutic agent selected from the group consisting of: a FoxA2 receptor-specific antibody that stimulates the activity of the receptor an isolated FoxA2 protein or proFoxA2 protein; and an isolated nucleic acid molecule encoding a FoxA2 protein or proFoxA2 protein, wherein the nucleic acid molecule is operatively linked to a transcription control sequence; b. measuring a change in lung function in response to a provoking agent in the mammal to determine if the FoxA2 therapeutic agent modulates airway hyperresponsiveness; and c. prescribing a pharmacological therapy comprising administration of FoxA2 therapeutic agent to the mammal effective to reduce inflammation based upon the changes in lung function.

26. A method of prophylactically treating a subject at risk of developing an airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response, the method comprising administering to the subject a therapeutically effective amount of a formulation comprising a FoxA2 therapeutic demonstrated to inhibit onset of the respiratory disease.

27. A method of improving gas exchange in the lungs of a subject comprising identifying a subject for whom an improvement in gas exchange within the lungs would be beneficial; providing a therapeutically effective amount of a formulation comprising a FoxA2 therapeutic demonstrated to impove gas exchange within the lungs to the subject for inhalation, and before, during, or immediately after the FoxA2 therapeutic is inhaled by the subject, introducing into the subject a therapeutically-effective amount an anti-inflammatory agent.

28. The method of claim 27, wherein the anti-inflammatory agent is selected from the group consisting of anti-IgE, immunomodulating drugs, leukotriene synthesis inhibitors, leukotriene receptor antagonists, glucocorticosteroid, steroid chemical derivatives, anti-cyclooxygenase agents, beta-adrenergic agonists, methylxanthines, cromones, anti-CD4 reagents, anti-IL-5 reagents, surfactants, cytoxin, and heparin.

29. The method of claim 27, wherein the anti-inflammatory agent is a glucocorticoid selected from the group consisting of budesonide, rofleponide, beclomethasone dipropionate, beclomethasone monopropionate, ciclesonide, tipredane, flunisolide, triamcinolone acetonide, and fluticasone propionate, wherein said glucocorticoid substance is released in the lower part of the small intestine or the upper part of the large intestine, and wherein the glucocorticoid substance is administered in an amount that is therapeutically effective for the treatment of airway inflammation in the patient.

30. The method of claim 27, wherein the subject is hypoxic.

31. The method of claim 27, wherein the subject is a human suffering from a lung injury.

32. A formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a FoxA2 therapeutic agent selected from the group consisting of: a FoxA2 receptor-specific antibody that stimulates the activity of the receptor; an isolated FoxA2 protein or proFoxA2 protein; and an isolated nucleic acid molecule encoding a FoxA2 protein or proFoxA2 protein, wherein the nucleic acid molecule is operatively linked to a transcription control sequence.

33. The formulation of claim 32, wherein the formulation comprises a pharmaceutically acceptable excipient.

34. The formulation of claim 32, wherein the formulation comprises a controlled release vehicle selected from the group consisting of biocompatible polymers, other polymeric matrices, capsules, microcapsules, microparticles, bolus preparations, osmotic pumps, diffusion devices, liposomes, lipospheres, viral vectors and transdermal delivery systems.

35. The formulation of claim 32, wherein the FoxA2 therapeutic agent is an isolated FoxA2 protein or proFoxA2 protein.

36. The formulation of claim 32, wherein the FoxA2 therapeutic agent is an isolated nucleic acid molecule encoding a FoxA2 protein or proFoxA2 protein, wherein the nucleic acid molecule is operatively linked to a transcription control sequence.

37. The formulation of claim 36, wherein the isolated nucleic acid molecule is complexed with a liposome delivery vehicle.

38. The formulation of claim 36, wherein the isolated nucleic acid molecule in a viral vector delivery vehicle.

39. The formulation of claim 38, wherein the viral vector delivery vehicle is from adenovirus.

40. The formulation of claim 32, wherein the FoxA2 therapeutic agent is a FoxA2 receptor-specific antibody that stimulates the activity of the receptor.

41. The formulation of claim 32, wherein the FoxA2 therapeutic agent is selected from the group consisting of: an isolated FoxA2 protein or proFoxA2 protein and an isolated nucleic acid molecule encoding a FoxA2 protein or proFoxA2 protein, wherein the nucleic acid molecule is operatively linked to a transcription control sequence.

42. The formulation of claim 32, wherein the anti-inflammatory agent is selected from the group consisting of anti-IgE, immunomodulating drugs, leukotriene synthesis inhibitors, leukotriene receptor antagonists, glucocorticosteroids, steroid chemical derivatives, anti-cyclooxygenase agents, beta-adrenergic agonists, methylxanthines, cromones, anti-CD4 reagents, anti-IL-5 reagents, surfactants, cytoxin, and heparin.

43. The composition according to claim 32 further comprising a phospholipid selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, hydroxylated lecithin, distearoylphosphatidylcholine, phosphatidylserine, phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, sphingomyelin, dimyristoylphosphatidylcholine, dimyristoylphosphatidylglycerol, and mixtures thereof in an amount ranging from about 1% to about 20% by weight of said composition.